

## **ATHLETE S FOOT AFAC- clotrimazole cream**

**Natureplex, LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **Athlete s Foot**

### **Afac**

### ***Drug Facts***

### **Active ingredient**

Clotrimazole 1%

### **Purpose**

Antifungal

### **Uses**

- cures most athlete's foot, jock itch, and ringworm
- relieves itching, burning, cracking, scaling and discomfort which accompany these conditions

### **Warnings**

#### **For external use only**

**Do not use** on children under 2 years of age unless directed by a doctor.

#### **When using this product**

- avoid contact with the eyes

#### **Stop use and ask a doctor if**

- irritation occurs
- there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch)

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

### **Directions**

- wash affected area and dry thoroughly
- apply a thin layer over affected area twice daily (morning and night)
- supervise children in the use of this product
- for athlete's foot, pay special attention to spaces between the toes, wear well fitting, ventilated shoes and change shoes and socks at least once daily
- for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks
- if condition persists longer, ask a doctor
- this product is not effective on the scalp or nails

### **Other information**

- store between 15°- 30°C (59°- 86°F)

- do not use if seal on tube is punctured or missing

**Inactive ingredients**

Aloe barbadensis (aloe) leaf juice, carbomer, cetyl alcohol, DMDM hydantoin, glyceryl monostearate, isopropyl alcohol, methylparaben, mineral oil, polysorbate 20, propylparaben, purified water, stearic acid, triethanolamine, trisodium EDTA

**Questions or comments?**

call 866-323-0107 or visit [www.natureplex.com](http://www.natureplex.com)

**PRINCIPAL DISPLAY PANEL - 35 g Tube Carton**

*Natureplex™*

***Athlete's Foot***  
***clotrimazole cream***

NET WT. 1.25 Oz. (35g)



clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67234-009
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Clotrimazole (UNII: G07GZ97H65) (Clotrimazole - UNII:G07GZ97H65)	Clotrimazole	0.01 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TRIETHANOLAMINE DODECYLBENZENESULFONATE (UNII: 8HM7ZD48HN)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67234-009-01	35.5 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	01/22/2008	

Labeler - Natureplex, LLC (062808196)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex, LLC		062808196	manufacture(67234-009)

